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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,129	04/11/2001	Michele Fiscella	PZ045P1	1593

22195 7590 07/02/2003

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EXAMINER
ROBINSON, HOPE A

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/02/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/832,129	FISCELLA ET AL.	
	Examiner	Art Unit	
	Hope A. Robinson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,13,15,17-20,22 and 24-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *15 and 25-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The preliminary amendment filed on May 9, 2003 has been received and entered.

2. Applicant's election with traverse of Group II (subgroups 24-46), claims 11-12 and 15 (SEQ ID NO: 35) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the claims not be restricted because there is no serious burden. Applicant contends that the search of a polynucleotide would provide useful information for examining claims directed to both polynucleotide and polypeptides. Applicant further asserts that the searches of polynucleotides, polypeptides, antibodies and methods of diagnosing and treating disease states, using the protein of the invention are overlapping. The restriction requirement clearly set forth the differences between the groups of inventions and established that the inventions have acquired a separate status in the art based on the classification, thus would impose a serious burden. However, burden is not the only criteria for making a restriction requirement as the MPEP chapter 800 sets forth that restrictions are proper if the inventions are independent and distinct which was also demonstrated in the restriction requirement. Therefore, the restriction requirement is proper and is final.

Claim Disposition

3. Claims 2-12, 14, 16, 21 and 23 have been canceled. Claims 24-46 have been added. Claim 17 has been amended. Claims 1, 13, 15, 17-20, 22 and 24-46 are pending. Claims 15 and 25-46 are under examination. It is noted that applicant canceled claims 11-12 of the elected group and submitted new claims 25-46.

Claim Rejections - Utility Rejections Under 35 U.S.C. § 101 And 35 U.S.C. 112, First Paragraph

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 15 and 25-46 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. The present application on page 2 refers to the invention as " relating to a polynucleotides and the encoded polypeptides, vectors, host cells, antibodies and recombinant/synthetic methods of producing the polypeptides and polynucleotides. Also diagnostic methods for detecting diseases/disorders related to the polypeptides and therapeutic methods for treating diseases/disorders. Further, the invention relates to screening methods for identifying binding partners of the polypeptides. The claims are

directed to an isolated protein comprising SEQ ID NO: 35 and fragments of the protein. No function of the protein *per se* is set forth in relationship to a specific disease. No activity assays are presented for the protein set forth in SEQ ID NO: 35, nor a specific binding molecule such as a receptor identified. No well established utility exists for the newly isolated protein. Since the specification sets forth no specific function for the claimed protein, the polynucleotide encodes a protein with no ascribed function. On page 11, the specification asserts that a polypeptide and polynucleotide can be useful as reagents for differential identification of the tissue(s) or cell type(s) present in a biological sample and for diagnosis of diseases and conditions which include but are not limited to: neural diseases and/or disorder, particularly neurodegenerative conditions and brain tumors. Similarly, polypeptides and antibodies directed to these polypeptides are useful in providing immunological probes for differential identification of the tissue(s) or cell type(s). It is also stated that the polypeptides and polynucleotides would be useful for treatment, detection, diagnosis and/or prevention of cancer, particularly brain, bladder, ovarian or skin cancer, squamous carcinoma, renal cell carcinoma or squamous cell oesophageal carcinoma (page 12). The specification points to Examples 11, 15 and 18 as exemplification. Example 11 provides the production of secreted proteins for high throughput screening assays, Example 15 provides a high throughput screening assay for identifying neuronal activity and Example 18 provides a high throughput screening assay for identifying changes in small molecule concentration and membrane permeability. A review of Examples 11, 15 and 18 (shows fluorescence) indicates that supernatant was generated. Clearly, these examples do not provide evidence of a polypeptide that is to be used as described above. Note that no data is provided to support the asserted function. Therefore, the application is devoid of

description of utility and working examples of the presently claimed protein function, which is neither clearly defined nor demonstrated.

The specification asserts that the protein can be used as treatment or prevention of cancer for example. This assertion is credible and specific but not substantial. The specification does not disclose any particular conditions wherein there is a deficiency, overproduction, or altered form of the claimed protein. There is no evidence, for example, that the protein is not expressed in healthy tissues. Even if the gene was differentially expressed in cancerous tissues, for example, there is no indication regarding how to develop a drug to treat cancer based on the claimed protein, because there is no information disclosed regarding the role the protein plays in healthy tissue. Significant further experimentation would be required of the skilled artisan to identify individuals who would benefit from such a drug, and then to determine a best course of treatment. Since the asserted utility is not presented in a mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

The specification also asserts that the protein can be used in diagnosing disease for example cancer, this asserted utility is credible and specific, however, it is not substantial. The specification does not disclose any specific diseases associated with altered levels or forms of the protein. There is no disclosure, for example, of any symptoms associated with such a disease. Thus, this asserted utility is not substantial as one of skill in the art would have to engage in further experimentation.

The specification gives the utility of a probe, this utility is credible and substantial, however, not specific as this can be done with any polynucleotide.

In view of the foregoing, it is apparent that the present application lacks a specific and substantial utility especially where there is also an absence of exemplification.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 15 and 25-46 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

6. Claims 15 and 25-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a protein encoded by a gene deposited at ATCC and methods of making the protein. However, the specification lacks adequate written description with regard to the deposit information. It is noted that page 4 of the specification indicates where the clones are deposited and that the deposit is under the

Budapest Treaty, however, there is not disclosure as to the whether the clones are readily available thus is considered insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met. Without publicly available deposit information one of skill in the art could not be assured of the ability to practice the invention as claimed. Amendment of the specification to disclose the date of the deposit is required. For further information concerning deposit practice, applicants attention is directed to *In re Lundak* 773 F 2d 1216 227 USPQ CAFC and 37 CFR 1.801-1.809.

Claim 37 is directed to an isolated protein comprising an amino acid sequence at least 90% identical to amino acid residues 1 to 766 of SEQ ID NO: 35 and the claim has no limitations to the function of the protein (see also claims 38-46). Therefore, these claims are drawn to a large variable genus of polypeptides with unknown activity or inactive variants. In addition, the unspecified variants have not been adequately described in the instant specification as no special features or characteristics for the variants are provided. Therefore, the specification fails to describe representative species by identifying characteristics or structural properties other than having sequence similarity to SEQ ID NO: 35. Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize that applicants were in possession of the invention as claimed.

The specification provides no measurable end point to allow one of skill in the art to be able to determine if a polypeptide that is in possession of another, and having at

least 90% identity to SEQ ID NO:35, for example, falls within the description of the polypeptides as claimed. The specification does not describe polynucleotides encoding polypeptides having at least 90% identity to SEQ ID NO: 35 and do not have the asserted function, for example. The claims must recite a specific, measurable activity such that one can recognize a polypeptide as that claimed, or a fragment thereof.

Therefore, at the time the application was filed, would not have taught one skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 112, second paragraph as failing to distinctly point out the subject matter applicant regards as his invention.

Claim 15 is indefinite because the claim depends from a canceled claim.

Conclusion

8. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703) 308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 6:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, Ph.D., can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS

Patent Examiner

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